DEPARTMENT OF HEALTH AND HUMAN SERVICES

NOV 5 1996

Dr. Kent Croon
Regulatory Affairs Manager
Monsanto Company
700 Chesterfield Parkway North
Chesterfield, Missouri 63198

Dear Dr. Croon:

This is in regard to Monsanto's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on genetically modified corn, specifically transformation events MON 802, 805, 830, 831, and 832. According to Monsanto, the new corn varieties designated MON 802 and 805 are insect-protected Roundup Ready™ lines that produce i) the CryIA(b) pesticidal protein derived from *Bacillus thuringiensis* subsp. *kurstaki* (Btk protein) and ii) the 5-enolpyruvylshikimate-3-phosphate synthase protein derived from *Agrobacterium* sp. strain CP4 (CP4 EPSPS protein) and the glyphosate oxidoreductase protein (GOX protein) from *Ochrobactrum anthropi* (formerly *Achromobacter*), which confer tolerance to glyphosate, the active ingredient in the herbicide Roundup®. The new corn varieties designated MON 830, 831, and 832 are Roundup Ready™ lines that produce only the CP4 EPSPS and GOX proteins; hence, these lines are tolerant to applications of glyphosate herbicide.

On March 10, 1995, Monsanto met with FDA to discuss the proposed safety and nutritional assessment of corn containing transformation events that confer pesticidal activity and herbicide tolerance. As part of bringing the consultation regarding these products to closure, Monsanto submitted a summary assessment of corn containing transformation events MON 802, 805, 830, 831, and 832 on July 2, 1996.

These communications informed FDA of the steps taken by Monsanto to ensure that these products comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessments you have conducted, it is our understanding that Monsanto has concluded that corn grain (kernels), fodder, and silage derived from the new varieties are not materially different in composition, safety, and other relevant parameters from corn grain (kernels), fodder, and silage currently on the market, and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0035. This file will be maintained in the Office of Premarket Approval.

Based on the information Monsanto has presented, we have no further questions concerning corn containing transformation events MON 802, 805, 830, 831, and 832 at this time. However, as you are aware, it is Monsanto's responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely,

/S/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center Food Safety
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-226 HFS-235 HFS-246 HFS-247
HFS-13 HFS-144 HFV-151 HFV-200 HFV-221 HFV-228 BNF0035
HFS-206 HFS-326(VKB;MOD I)